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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/589,376   | 08/14/2006  | Hideyuki Miyake      | CU-5009 BWH         | 6031             |
| 26530 7590 01/29/2010<br>LADAS & PARRY LLP<br>224 SOUTH MICHIGAN AVENUE<br>SUITE 1600<br>CHICAGO, IL 60604 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| KOSAR, AARON J   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1651   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/589,376

**Applicant(s)**

MIYAKE ET AL.

**Examiner**

AARON J. KOSAR

**Art Unit**

1651

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-11, 13 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-11, 13 and 15-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 10, 2009 has been entered.

***Response to Amendment***

Applicant's amendment and argument filed September 10, 2009, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Applicant has amended the claims by adding new claims 15-21. Claims 7-11, 13, and 15-21 are pending and have been examined on their merits.

***Claim Objections***

Claim 21 is objected to because of the following informalities: The term "cultureing" in line 4 appears to be an inadvertent typographical error of the term – culturing --.

Appropriate correction is suggested.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7-11, 13, and 15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7, 11, and 21 recite "a cell" and "the cell" (for example in lines 4,5,7,11,and 13 of claim 7); however, the claims recite "the cells" (e.g. in lines 13 and 15 of claim 7) and it is unclear what cell quantity (i.e. a cell vs. cells) Applicant intends by the claims. Clarification is required.

Claims 7 recites "a cell adhesion portion" and "the cell adhesion portion" in lines 9, 14, and 15 and recites "two cell adhesion portions" in line 13; however, it is unclear what quantity of cell adhesion portion(s) Applicant intends by the claims. Clarification is required.

Claims 7 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting

to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the feature(s) and arrangement(s) within the substrate which qualify or disqualify the features/arrangements thereof which "inhibits adhesion to the cell". Thus it is unclear how the "cell non-culture region" and the "cell adhesion auxiliary portion" are structurally related or distinguished from each other and within the substrate. Clarification is required.

In claims 17-20 the claims recite the phrase "is capable of being decomposed or denatured by the action of a photocatalyst upon irradiation with energy"; however, it is unclear in each instance of the phrase if Applicant intends for the phrase to further limit the "layer" or "portion"), the "material" contained therein, or if another interpretation is intended. Clarification is required.

Claim 21 recites the limitation "the cell adhesion auxiliary portion" in lines 8, 10, 11, and 13. There is insufficient antecedent basis for this limitation in the claim. Clarification is required..

All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under 35 USC § 112, second paragraph, for the reasons set forth above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).*

Claims 7-11, 13, and 15-21 are/remain rejected as obvious over Singhvi (U.S. Patent No. 6,368,838 B1, of record).

A patterning substrate composition comprising a base material having cell culture and a non-culture regions is claimed. Additionally, the claims are drawn to a patterned substrate having an inter/intra concave:convex distances of 0.5-10  $\mu\text{m}$ .

Singhvi teaches a substrate comprising a baseplate or substrate and a plurality of cytophilic/biophilic islands isolated by cytophobic/biophilic regions (see whole document, e.g. abstract; figure 1). Singhvi also teaches an array grid formed from a linear template, including an electron microscopy grid or parallel lines or from any corrugated pattern and that the pattern may be obtained from photolithography (e.g. column 4, lines 54-67; column 22, examples 1 and 3).

Singhvi does not teach a preferred combination of shape, dimension, or pattern of the cell-binding and cell-nonbinding regions as instantly claimed (e.g. 0.5-10  $\mu\text{m}$ ).

It would have been obvious to a person of ordinary skill in the art at the time the instant invention was made to have provided a substrate having the features of: 0.5-30  $\mu\text{m}$  distances, concavoconvex shapes, and/or linear arrangements. It would have been obvious to have provided a plate/substrate having the features of 0.5-30 micrometer distances, concavoconvex shapes, and/or linear arrangements (herein referred to collectively as “the preferred features”), because Singhvi teaches manipulations of the morphology of the patterned plate.

One would have been motivated to modify the plate to have the preferred features, because Singhvi teaches configurations and methods of modifying the configurations, including: (1) adjusting to vary the island size relative to the desired cell dimensions, including teaching of 20 micrometer white blood cells and 1 micrometer *Xenopus* oocytes (column 12, ¶3-4); (2) adjusting an island area or shape, including “any size or shape, including rectilinear, circular, ovoid, and arbitrary shapes” (column 11, ¶ 3, emphasis added); and arranging in [linear] arrays, including grids wherein “irrespective of the shape of the islands, a pattern consisting of an array of islands is referred to as a grid” or parallel lines (column 11, ¶ 3-4; figure 1).

One would have had a reasonable expectation of success in making the composition having the preferred features, because the alteration of a micro array for cell adhesion and the modes of manipulation thereof are taught by Singhvi and the selection and optimization of a particular arrangement would be well within the purview of the skilled artisan.

Additionally, Singhvi is relied upon for the reasons discussed above. If not expressly taught by Singhvi, based upon the overall beneficial teaching and methods provided by this reference with respect shapes, sizes, and arrangements of the islands in the manner disclosed therein, including the teachings of using shapes with curvature (concave or convex, e.g. patterning with circular and ovoid shapes or corrugated patterns) and providing instruction on tailoring islands and spacer regions to a cell morphology, the selection of a particular shape and arrangement of islands and spacer regions (cell adhesion, non-adhesion, and/or adhesion-inhibiting regions) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

#### ***Response to Arguments***

Applicant has argued that the object of the present invention is to provide a substrate on which cells can be arranged regularly with high efficiency over a large area so as to obtain formation of a tissue and that the prior art does not teach binding across the cell-nonbonding



region. Applicant also has argued that the Singhvi does not teach culturing in the entire region (cell-binding and cell-nonbinding regions) and that “even when the cell culture region is a large area, the cell arrangement and morphological change can be made excellent”. Applicant has further argued that Singhvi would lead one of skill to widen cell-nonbinding regions such that binding would not occur over the nonbinding region.

In response to Applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., cell arrangement and some further-undisclosed efficiency thereof; an area or size thereof; large cell culture area; a cell or cells and preferred attachment(s) thereof) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to Applicant's argument that the prior art structure is incapable of performing the intended use (binding across cell-nonbonding portions, formation of a tissue, culturing in the entire region) or that Singhvi teaches widening the non-bonding region, this, is found to be not persuasive, because Singhvi teaches that the composition is capable of providing cell-cell contact across nonbonding portions to culture/form a tissue by teaching “cells...are allowed to form bridges across the cytophobic regions and contact each other” (see whole document, e.g. Abstract); and Singhvi still renders obvious the size and shape (concavo-convex pattern and 5-10 $\mu$ m width) by teaching that the composition may be provided with any pattern, e.g. a corrugated-, micromachined-, or photolithographed-pattern and having dimensions of about 10 to about 0.25  $\mu$ m (concavoconvex successively formed, 0.5-10 $\mu$ m width) (e.g. columns 4-7, esp.

col. 4 lines 54-67 and col.7 lines 2-5), then the structure of Singhvi still renders obvious the pattern and dimensions thereof, as instantly claimed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/  
Examiner, Art Unit 1651

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655